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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,501	04/22/2002	Hiroyuki Saito	053-466-0325	9449
22428 7590 09/25/2009 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER BURKHART, MICHAEL D	
			ART UNIT	PAPER NUMBER
			1633	
			MAIL DATE	DELIVERY MODE
			09/25/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/089,501

**Applicant(s)**

SAITO ET AL.

**Examiner**

Michael Burkhardt

**Art Unit**

1633

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 04 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

/Michael Burkhardt/  
Primary Examiner, Art Unit 1633

Continuation of 11, does NOT place the application in condition for allowance because: Claims 45-49, 52, 53 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al (U.S. Patent 5,986,065, EFD 3/10/1997). This rejection is maintained for reasons made of record in the Office Actions dated 4/4/2008, 12/23/2008, 6/4/2009, and for reasons set forth below.

#### Response to Arguments

Applicant's arguments filed 3/23/2009 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) Wong et al fail to teach suppressing "hypertrophy of the vascular intima" as inherency cannot be relied upon in this instance, and the PTO has not pointed out where this particular limitation is taught by Wong et al; 2) Applicants have not equated "hypertrophy of the vascular intima" with restenosis, as asserted by the Examiner; 3) restenosis can be early or late stage, and the presently claimed methods are directed to late stage restenosis as opposed to Wong et al, which is directed to early stage, as evidenced by an excerpt from The Heart (2004); 4) Wong et al does not teach treating restenosis as a whole, but rather treating thrombosis, thus Wong et al do not teach treating "hypertrophy of the vascular intima."

Regarding 1) and 4), it has been pointed out, using column and line number, where treating restenosis (a form of "hypertrophy of the vascular intima") is taught by Wong et al using the same antibodies recited in the instant claims. Again, see col. 3, lines 18-37, and co. 5, 19-35. This is not a reliance upon inherency, but rather a specific teaching by Wong et al of a claim limitation.

Regarding 2), a quote from page 7 of applicants reply dated 12/1/2008 reads: "Hypertrophy of the vascular intima, e.g. restenosis, involves the formation of new blockages at the side [sic] of angioplasty or stent placement." This statement clearly evinces that restenosis is an example of "hypertrophy of the vascular intima." There is literally no alternate interpretation of this sentence. Applicants replied dated 3/23/2009 is much the same, a quote from page 4 is as follows: "Restenosis is the name given to the formation of new blockages within an artery, after the artery has been treated with angioplasty or stenting. For example, restenosis is the renarrowing of a coronary artery after angioplasty." Again, this is an interpretation of restenosis that lies within the bounds of the term "hypertrophy of the vascular intima", and correlates with the conditions used in the instant specification in order to induce hypertrophy of the intima, i.e. Example 6, beginning on page 40. Furthermore, a reading of this example provides further equivalence of restenosis with "hypertrophy of the vascular intima", as this Example states that the claimed antibodies would "effectively prevent restenosis."

Regarding 3), In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., treating only late stage restenosis) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further regarding 3), the reference applicants rely upon has not been made of record and is considered an assertion, at best. "Argument of counsel cannot take the place of evidence lacking in the record." *In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974).

Further regarding 4), the interpretation of "hypertrophy of the vascular intima" is considered to be as stated in the Office Action dated 12/23/2008: "Hypertrophy" is loosely a growth of non-tumorous nature and "intima" is considered to be the innermost membrane of a vein, vessel, etc. This would appear to encompass both early and late stage restenosis in spite of applicants protests to the contrary, as thrombosis is a "growth of non-tumorous nature." Furthermore, since the antibodies of Wong et al have the same activity as those instantly claimed, they inherently have the same effect upon restenosis as the claimed antibodies. Finally, it is noted the only working example of the claimed methods in the specification would appear to treat early stage, or early and late stage, restenosis due to the temporal aspect of administration of the claimed antibodies before vascular injury, and thus long before any late stage restenosis could occur (see the sentence bridging pages 40 and 41). Thus, the patient group "in need thereof" to be treated by the instant claims and by Wong et al would appear to be the same.